REMARKS

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments, remarks and enclosures herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-13 and 15-22 were pending in this application. Claims 9 and 14-19 have been canceled. Claims 1, 5, 6, 8, 10, 12, 20 and 21 have been amended for clarity without prejudice, without admission, without surrender of subject matter and without any intention of creating any estoppel as to equivalents. New claims 22-24 have been added.

Claim 1 has been amended to recite a viscosity regulating agent. Support may be found in paragraph [0027] of the specification as published. Claim 1 was further clarified to recite "wherein no water is added to the formulation". Support may be found in paragraphs [0053] and [0054] of the specification as published. Claim 5 has been clarified to recite oil in an amount of 90% by weight of the formulation, claim 8 has been clarified to recite component (c) in an amount of between 1% and 5% by weight of the formulation, and claim 12 has been clarified to recite a viscosity regulating agent in an amount of between 1% and 3% by weight of the formulation. Support for claims 5, 8 and 12 may be found in paragraphs [0023], [0026], and [0030], respectively, in the specification as published. Claim 20 was clarified to recite a sexual hormone drug in an amount of between 2% and 4% by weight of the formulation, and claim 21 was clarified to recite a sexual hormone drug in an amount of 2% by weight of the formulation. Support for claims 21 and 22 may be found in paragraph [0032] of the specification as published.

Support for new claim 22 may be found throughout the specification as filed and in the pending claim listing. Support for new claim 23 may be found in Figure 1 of the instant application. Support for new claim 24 may be found in paragraphs [0063] and [0065] of the specification as published.

No new matter is added.

It is respectfully submitted that the claims, herewith and as originally presented, are patentably distinct over the art, and that those claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, the amendments and remarks herewith are made simply for clarification and to round out the scope of protection to which Applicant is entitled.

II. THE 35 U.S.C. §103 REJECTIONS ARE OVERCOME

Claims 1-6, 8, 13, 15-17 and 20-21 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Illum (US 5,863,554) in view of Ko *et al.* (Journal of Microencapsulation 1998) ("Ko").

Applicant respectfully disagrees and traverses the rejection.

The Examiner is respectfully directed to the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Although a teaching, suggestion, or motivation to combine is no longer rigidly required for a finding of obviousness, it remains the primary guarantor against a non-statutory hindsight analysis. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Further, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." For the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicant's disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988).

Applying the law to the instant facts, the references relied upon by the Office Action does not disclose, suggest or enable Applicant's invention.

The Office Action alleges that Illum teaches most elements of the claimed invention but is deficient in its teaching of a drug delivery system comprising testosterone. Apparently, to make up for this deficiency, the Office Action cites Ko, asserting that this references teaches emulsion formulations of testosterone for nasal delivery. The Office Action concludes that it would have been obvious to combine the two references to arrive at the presently claimed invention. See Office Action at page 8. Applicant respectfully disagrees.

As clarified herein, claim 1 recites (a) a sexual hormone drug in an amount of between 0.5% and 6.0% by weight of the formulation, (b) at least one oil in an amount of between 85% and 95% by weight of the formulation, and (c) a viscosity regulating agent, wherein no water is added to the formulation. Applicant respectfully submits that neither Illum nor Ko teach or suggest an oil concentration of 85% to 95% by weight of the formulation, a viscosity regulating agent, or a water-free formulation.

With respect to the lipophilic nature of the cited compositions, in the previous Office Action mailed November 13, 2007, the Examiner asserted that Illum discloses a highly lipophilic concentration in the compositions for microspheres. The Office Action states specifically, "In the compositions for the gelatin microspheres and the chitosan microspheres, 90% of olive oil (100 ml out of 110 ml total solution) and soybean oil (100 ml out of 110 ml total solution) was used respectively (Col. 7, lines 14-41)."

Applicant submits that the Examiner's conclusion relating to the used percentages of oil is incorrect. The 110 ml volume recited was the volume used for the generation of the microspheres, consisting solely of, for example, olive oil and gelatin. This volume can in no way be extrapolated to 90% oil by weight of the [administered] formulation. The referenced microsphere compositions do not contain an active nor do they contain a viscosity regulating agent. Illum does not disclose the weight percentage of oil in its formulation.

Similarly, Ko does not disclose a lipophilic formulation having oil present at an amount of between 85% and 95%. Rather, Ko relates to a formulation having 45% oil by weight of the formulation (See page 199, paragraph 2, 40 g of soybean oil in 50 g phthalate buffer).

Further, Applicant submits that both Illum and Ko require the addition of water to the formulation. In particular, both references require formulations prepared by oil and water emulsions. Water is not added to the presently claimed formulation.

With respect to the concentration of the sexual hormone drug in the formulation, Applicant submits that neither Illum nor Ko teach or suggest particular concentrations of testosterone to be used in the formulation, and they especially do not recite concentrations of 0.5% to 6%. The Examiner stated in the Office Action mailed May 5, 2008 that recited percentages of the sexual hormone drug are "obvious variants unless there is evidence of criticality or unexpected results". See May 5, 2008 Office Action at page 8.

Applicant respectfully direct the Examiner's attention to the case law, which has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are…ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of

others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727.

Applicant submits that one of the novel, unexpected and advantageous aspects of the presently claimed invention is the high bioavailability of the active ingredient resulting in higher serum levels of the active for a prolonged period of time (e.g. at least 10 hours, See Example 1 of instant specification). Such a finding differs from what is typically found in the art, for example, in Ko, which showed that testosterone concentration is gradually reduced over a mere 4 hour period of time. The formulation of the present application allows for a higher availability of even a small concentration of testosterone (e.g. $\leq 2\%$ by weight of the formulation), which remains at high serum levels for a prolonged period of time.

In view of the foregoing, Applicant respectfully submits that neither Illum nor Ko teach or suggest the presently claimed, highly lipophilic, water-free formulation, thus, reconsideration and withdrawal of the rejection of claims 1-6, 8, 13, 15-17 and 20-21 under Section 103 are respectfully requested.

Turning now to the rejections of the remaining claims, claims 9-10, 12, and 18-19 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Illum in view of Ko and further in view of Dondeti (international Journal of Pharmaceutics 1996), claim 7 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Illum in view of Ko and further in view of Patel *et al.* (US 6,248,363) ("Patel"), claim 11 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Illum in view of Ko and further in view of Glass (US 5,897,894), and claim 22 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Illum in view of Ko and further in view of Bechgaard et al. (US 5,397,771) ("Bechgaard"). Claims 9, 18-19, and 22 have been canceled and the subject matter incorporated into claim 1. Applicant traverses this rejection for the reasons stated above, in particular, that Illum and Ko cannot be combined and used as a proper references cited under Section 103. Illum, Ko, Dondeti, Glass, Patel, and Bachgaard, even combined, do not teach or suggest highly lipophilic, water-free formulation having a sexual hormone drug at 0.5% to 6% by weight of the formulation, and having a viscosity regulating agent.

Turning now to new claim 22, Applicant submits that none of the references cited teach or suggest a formulation with all components present, and especially no not teach or suggest said components in the recited weight percentages of the formulation.

Regarding new claims 23 and 24, Applicant submits that none of the references cited teach or suggest a formulation wherein after a single application of the formulation, the level of unbound sexual hormone drug is constant over at least 6 or 10 hours, mimicking the physiologic daily rhythm of hormone release.

In view of the foregoing, Applicant respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

III. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 1-8, 10-12, 15, 18-19 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 10-12, 16, 18-21 and 24-25 of copending Application No. 11/560,187.

Applicant submits that a Terminal Disclaimer was filed on October 14, 2008.

Accordingly, reconsideration and withdrawal of the double patenting rejection are respectfully requested.